UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,373	05/04/2005	Diego A. Gianolio	4830-13PUS	8655

27799 7590 03/17/2008

COHEN, PONTANI, LIEBERMAN & PAVANE
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

EXAMINER	
LAU, JONATHAN S	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,373	GIANOLIO ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action details a Restriction Requirement and a First and Second Election of Species Requirement.

Restriction Requirement

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8 and 11-15, drawn to a compound comprising hyaluronan cross-linked with a polyfunctional cross-linking agent having two or more aziridines and methods of making thereof.

Group II, claim(s) 9, 10 and 16, drawn to a pharmaceutical composition comprising the compound of claim 1 and a pharmacologically active agent and methods of making thereof.

Group III, claim(s) 17 and 18, drawn to a method of preventing post-operative surgical adhesions of tissue comprising providing the tissue surfaces involved in said surgery with a hydrolyzable coating comprising a compound comprising hyaluronan cross-linked with a polyfunctional cross-linking agent having two or more aziridines.

Group IV, claim(s) 19, drawn to a method of preventing post-operative surgical adhesions of tissue comprising providing the tissue surfaces involved in said surgery with a hydrolyzable coating comprising a compound comprising hyaluronan cross-linked with a polyfunctional cross-linking agent having two or more aziridines and a pharmacologically active agent.

Group V, claim(s) 20, drawn to a method of viscosupplementation for medical purposes which comprises contacting body tissue with a biocompatible viscoelastic gel slurry comprising a compound comprising hyaluronan cross-linked with a polyfunctional cross-linking agent having two or more aziridines.

Group VI, claim(s) 21, drawn to a method of viscosupplementation for medical purposes which comprises contacting body tissue with a biocompatible viscoelastic gel slurry comprising a compound comprising hyaluronan cross-linked with a polyfunctional cross-linking agent having two or more aziridines and a pharmacologically active agent.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common feature of Groups I-VI is hyaluronan cross-linked with a polyfunctional cross-linking agent having two or more aziridines. However, such a compound, hyaluronan cross-linked with a polyaziridine, is a known product. See Balazs et al. (GB 2,151,244, provided by Applicant in IDS filed 14 Oct 2004), page 1, lines 35-41. Therefore said compound is not the special technical feature of a single general inventive concept. The special technical feature of the invention of Group I is the specific chemical structure of hyaluronan cross-linked with a specific cross-linking agent. The special technical feature of the invention of Group II is the specific composition comprising a hyaluronan cross-linked with a specific cross-linking agent and a specific pharmacologically active agent. The special technical feature of the invention of Group III is the specific method of providing the tissue surfaces involved in said surgery with a hydrolyzable coating comprising a compound comprising hyaluronan cross-linked with a specific cross-linking agent. The special technical feature of the invention of Group IV is the specific method of providing the tissue surfaces involved in said surgery with a hydrolyzable coating comprising a compound comprising hyaluronan cross-linked with a specific cross-linking agent and a specific pharmacologically active agent. The special technical feature of the invention of Group V is the specific method of contacting body tissue with a biocompatible viscoelastic gel slurry comprising a compound comprising hyaluronan cross-linked with a specific cross-linking agent. The special technical feature of the invention of Group VI is the specific method of contacting body tissue with a biocompatible viscoelastic gel slurry comprising a compound comprising hyaluronan cross-linked with a specific cross-linking agent a specific pharmacologically active agent.

Election of Species Requirements

Applicant is further required to elect from the following **first** election of species of cross-linking agent.

If Applicant elects the invention of Groups II, IV or VI, Applicant is required to elect from both the following **first** and **second** election of species requirements.

This application contains claims directed to more than one **first** species of cross-linking agent and more than one **second** species of pharmacologically active agent of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

First election of species:

Examples of species of cross-linking agent are as follows, disclosed for example in claim 1:

1,1',1"-methylidynetris-aziridine,

di[2-(1-aziridinyl)ethyl)]adipate, and

1,1'-(1,3-dioxo-1,3-propanediyl)bis-aziridine.

Second election of species:

Examples of species of pharmacologically active agent are as follows, disclosed for example in page 10, lines 15-29 of the specification:

non-steroidal anti-inflammatory drugs,

cytotoxic agents, and

antibiotics.

Applicant is required, in reply to this action, to elect a single specie of cross-linking agent, such as 1,1',1"-methylidynetris-aziridine, and if Applicant elects the invention of Groups II, IV or VI, a single specie of pharmacologically active agent, such

as non-steroidal anti-inflammatory drugs, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-5 and 7-21 are generic to the species of cross-linking agent in the hyaluronan cross-linked with a polyfunctional cross-linking agent having two or more aziridines. Claims 9, 10, 16, 19 and 21 are generic to the species of pharmacologically active agent.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As recited above, the common feature of Groups I-VI is hyaluronan cross-linked with a polyfunctional cross-linking agent having two or more aziridines. However, such a compound, hyaluronan cross-linked with a polyaziridine, is a known product. See Balazs et al. (GB 2,151,244, provided by Applicant in IDS filed 14 Oct 2004), page 1, lines 35-41. Therefore said compound is not the special technical feature of a single general inventive concept. The special technical features of Groups I-VI are as recited above.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan S. Lau
Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623